UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/FLN)
This Document Relates to **ALL ACTIONS**	

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF MICHAEL KEEN, P.ENG., MBA

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INTRODUCTION

Plaintiffs' motion to exclude the expert opinions and testimony of Michael Keen, P.Eng., MBA, should be denied. Mr. Keen's testimony is relevant, reliable, and useful under Fed. R. Evid. 702 and Minn. R. Evid. 702, as it rebuts key issues concerning filtration of the Bair Hugger system and the potential negative impact (or lack thereof) of the Bair Hugger system on operating room airflows. Plaintiffs' criticisms of Mr. Keen's qualifications and the basis for his opinions are unfounded and should be rejected.

Mr. Keen is a mechanical engineer with more than three decades of experience in designing HVAC systems for hospitals and operating rooms. As Senior Director of Planning and Development at St. Michael's Hospital in Toronto, he has recently overseen a $300 million expansion that includes a doubling in size of the Emergency department. *See* http://www.stmichaelshospital.com/stmichaels3.0/index.php (last visited September 24, 2017). He is a long-standing member of the American Society of Heating, Refrigeration and Air Conditioning Engineers (ASHRAE), and helped to define the ventilation and filtration standards for American hospitals and operating rooms that remain in place today, and that serve as the foundation for his opinions.

In this case, Mr. Keen opines that the filter in the Bair Hugger system is appropriate for use in operating rooms, as it has an efficiency rating equal to that of the filtration required for hospital (and operating room) ventilation systems. *See* ECF No. 740-1, Expert Report of Michael Keen ("Keen Rept.") at 6-9. Mr. Keen will further testify regarding operating room airflow, and the fact that it is not negatively impacted by the Bair Hugger system. *See id.* at 9-16. These opinions are based upon Mr. Keen's years of training and

experience in designing HVAC systems for hospitals, as well as a thorough review and analysis of the more than 30 studies and publications referenced in his report – including his own, independent research. *See In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 412 (S.D.N.Y. 2016) ("Experts need not conduct studies of their own in order to opine on a topic; a review of other studies and scientific literature can be enough to qualify experts to testify and to make that proposed testimony reliable."). Mr. Keen's opinions are highly relevant to this litigation, as Plaintiffs challenge the efficiency of the Bair Hugger system filter and allege that the system negatively disrupts operating room airflow. Indeed, Plaintiffs offer the testimony of their own ASHRAE member and HVAC engineer, Daniel Koenigshofer, on exactly those points.

Plaintiffs' criticisms of Mr. Keen's opinions – whether they go to his qualifications or support for his opinions – are unfounded. For these reasons, and those discussed further below, Plaintiffs' motion should be denied.

ARGUMENT

Mr. Keen is a mechanical engineer with more than three decades of experience in designing HVAC systems for hospitals and operating rooms. He is a long-standing member of ASHRAE, and helped to define the ventilation standards for hospitals and operating rooms that remain in place today. Nevertheless, Plaintiffs claim that Mr. Keen is somehow unqualified to offer an opinion regarding the Bair Hugger filter or the

purported effect of the Bair Hugger system on operating room airflow. But Plaintiffs are wrong.[1]

I. MR. KEEN IS HIGHLY QUALIFIED TO OFFER OPINIONS REGARDING FILTERS USED IN THE BAIR HUGGER SYSTEM AND THE NEGATIVE IMPACT (IF ANY) OF THE BAIR HUGGER SYSTEM ON OPERATING ROOM AIRFLOW.

Among other things, Mr. Keen's testimony concerns efficiency of the Bair Hugger filter and whether it is appropriate for use in operating rooms, as well as the question of whether the Bair Hugger system has any discernible negative impact on operating room airflows. Mr. Keen is indisputably qualified to testify regarding such issues, as he has more than three decades of experience in designing HVAC systems for hospitals and operating rooms, and was directly involved in the development of the standards that define ventilation and filtration requirements for operating rooms to this day.

Mr. Keen is currently the Senior Director of Planning and Development for St. Michael's Hospital in Toronto, Ontario, Canada. *See* ECF No. 740-1, Keen Rept. at 1. He is a mechanical engineer with an Executive Master's Degree in Business Administration, and has substantial experience in the design, operation and maintenance of hospital facilities, including HVAC systems for operating rooms. *See id.* He has served as a member of ASHRAE for more than 20 years and, in particular, as part of the Member Standards Committee 170P, Ventilation of Health Care Facilities, since 2003. *See id.* at

[1] Plaintiffs also argue that Mr. Keen is not qualified to testify about the risk of infection during surgery, and should be precluded from testifying regarding "Canadian standards" or experiments by Michael Buck. *See* ECF No. 739, Pl. Mem. at 9, 13. Mr. Keen does not purport to offer testimony regarding such topics, however; Plaintiffs' arguments in this regard are thus irrelevant.

1-2. As part of his work with ASHRAE, he was the chair of the technical committee for healthcare, which was responsible for research activities, educational programs and technical publications related to HVAC systems in the healthcare industry. Since 2003, he has also been a member of the ASHRAE Standing Standard Project Committee (SSPC) 170, which was responsible for defining ventilation standards for healthcare facilities, including hospitals and operating rooms. *See id.* at 2. Standard 170 requires that HVAC systems supplying air to operating rooms "provide filtration to remove outdoor or recirculated contaminants at a MERV 14 rating." *Id*. at 3.

Mr. Keen has substantial expertise in the design, operation, and maintenance of hospital facilities, including operating rooms, and the design of HVAC systems. He is familiar with the various factors that must be considered in designing an operating room ventilation system, including temperature, humidity, filtration, relative pressurization, air changes, and airflow velocity and diffuser type. *See id.* at 2-3. Mr. Keen is also familiar with operating room airflow, including the specialized equipment used in some rooms to achieve "laminar" airflow, and turbulence that results from operating room equipment and staff, among other things. *See id.* at 9-12.

Mr. Keen's breadth of experience regarding operating room filtration and airflow confirms that he is qualified to provide the opinions offered in his report. Plaintiffs' claim to the contrary is without merit. *See, e.g.*, *In re Mirena*, 169 F. Supp. 3d at 413 ("[E]xpert testimony may be based on 'experience alone – or experience in conjunction with other knowledge, skill, training or education' . . . 'In certain fields, experience is the

predominant, if not sole, basis for a great deal of reliable expert testimony.'") (internal citations and quotations omitted).

II. MR. KEEN'S TESTIMONY REGARDING THE EFFICIENCY OF THE BAIR HUGGER SYSTEM FILTER IS RELEVANT AND RELIABLE.

Plaintiffs allege that the filter used in the Bair Hugger system is inadequate and renders the Bair Hugger system unreasonably dangerous. Mr. Keen provides the highly relevant rebuttal opinion, based upon his expertise and experience, that the filter meets ASHRAE's standards for filtration of air in the operating room.

First, in a throwaway argument, Plaintiffs assert that Mr. Keen is not qualified to render an opinion on the Bair Hugger filter. *See* ECF No. 739, Pl. Mem. at 5-6, 12-13. But it is difficult to imagine a witness who would be more qualified than Mr. Keen when it comes to air filtration in operating rooms. Plaintiffs do not dispute that ASHRAE Standard 170 defines the standards for operating room ventilation and filtration, and they do not dispute that those standards require filtration with a MERV 14 rating. As discussed above, Mr. Keen is a member of the ASHRAE committee that developed Standard 170 and established the MERV 14 requirement for operating rooms.

Plaintiffs also argue, inaccurately, that "Keen proposes to testify that the filtration standard for an operating room HVAC system should be applied to a medical device," and that "[h]e merely grafted a standard that applies to operating room design and construction (ASHRAE 52.2) onto a medical device." ECF No. 739, Pl. Mem. at 5-6. But Mr. Keen said no such thing. He has given the opinion only that the filter used in the Bair Hugger

system, which has a MERV 14 rating, meets ASHRAE's standard for filtration of air in the operating room:

> Q: [T]he opinion that you are preparing to offer is that ASHRAE should govern appropriate filter selection for a medical device, correct?
>
> A: That is not the opinion I am providing in the report.
>
> * * * *
>
> Q: [Y]ou have outlined and are prepared to offer the opinion that ASHRAE 170 and ASHRAE 52.2 govern the Bair Hugger in some manner:
>
> A: No, I have not offered that opinion.

DX1, Deposition of Michael Keen ("Keen Dep.") at 323:5-11, 325:21-24 (internal objections of counsel omitted).[2]

Indeed, as Mr. Keen explained, there is no specific requirement for filters used in medical devices – nor any requirement that medical devices use any filters at all. *See* ECF No. 740-1, Keen Rept. at 6; DX1, Keen Dep. at 183:3-6. He explains that the Bair Hugger system is notable for the fact that it includes a MERV 14 filter – thus satisfying the same filtration standards required of operating room ventilation systems. *See* ECF No. 740-1, Keen Rept. at 6-8. In forming his opinion, he reviewed the results of ASHRAE 52.2 filter tests performed on three models of Bair Hugger filters.[3] *See id.* Plaintiffs claim that Mr.

[2] Cites to "DX" are exhibits to the Declaration of Monica L. Davies filed concurrently with this opposition.

[3] ASHRAE Standard 52.2, Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size, is a standard method used to test and rate filters. ECF No. 740-1, Keen Rept. at 7.

Keen should be precluded from testifying regarding these tests because he did not conduct them himself and did not validate the methodology used. *See* ECF No. 739, Pl. Mem. at 12-13. Indeed, Plaintiffs argue that Keen's report "merely describes the content of an out of court test conducted by an unknown third party at the behest of 3M's litigation counsel" and that there is a "complete absence of information" regarding the methodology used. *Id.* at 13. Plaintiffs apparently did not read Mr. Keen's report very carefully. The report plainly states that one of the tests was conducted by 3M, and two were conducted by LMS Technologies. See ECF No. 740-1, Keen Rept. at 8. Mr. Keen's report also confirms that the ASHRAE 52.2 method was used, which is the standard method by which filters are tested and rated. *Id.* at 7-8. Reliance on such third-party testing is appropriate, and provides no basis on which to preclude Mr. Keen's testimony. *See In re Mirena*, 169 F. Supp. 3d at 412 ("Experts need not conduct studies of their own in order to opine on a topic; a review of other studies and scientific literature can be enough to qualify experts to testify and to make that proposed testimony reliable."); *see also Cedar Petrochemicals, Inc. v. Dongbu Hannong Chem. Co.*, 769 F. Supp. 2d 269, 284 (S.D.N.Y. 2011) ("Experts need not have actually collected the data on which they base their conclusions in order to be credible.").

III. MR. KEEN'S TESTIMONY REGARDING OPERATING ROOM AIRFLOWS IS ALSO RELEVANT AND RELIABLE.

When used as intended, the Bair Hugger system blows warm air through a perforated blanket and eventually escapes, primarily, through the head and neck area of the patient. *See* ECF No. 740-1, Keen Rept. at 13. This observation is consistent with

statements by McGovern and Belani, two of Dr. Scott Augustine's cohorts, both of whom reported that heat from the Bair Hugger exits in the area of the patient's head and neck. McGovern 2011 (ECF No. 829, p. 3) at 1538 ("Bubbles were introduced at the head/neck of the mannequin to track under-drape resident air movements in the region where the excess heat from patient warming was being released"); Belani 2013 (ECF No. 829, p. 95) at 407 (identical quote). Mr. Keen was asked to evaluate whether "forced air warming devices pose surgical site infection risk by disrupting the laminar airflow, allowing bacteria to enter the surgical site or impede the ventilation systems [sic] ability to remove contaminants from the surgical site." ECF No. 740-1, Keen Rept. at 13. Based on his review of relevant studies, including the same "bubble" studies upon which Plaintiffs rely, Mr. Keen concluded that they do not.

Mr. Keen evaluated the Augustine-sponsored "bubble studies" and found them unconvincing. As Mr. Keen explains, the bubbles used in the studies are significantly larger than particles that could be laden with bacteria in an operating room, "presenting a greater surface area to be impacted by airflow." *Id.* He noted that other studies have shown that bubbles are "generally not reliable to accurately represent airflow. When the bubbles are generated, they also have a starting velocity when they exit the bubble generator that may contribute to inaccuracies not representing true airflow impacts." *Id.*

Plaintiffs argue that Mr. Keen is not qualified to criticize the Augustine-sponsored bubble studies because "prior to his work on this case, [he] had never considered the use of neutrally buoyant bubbles in tracing or simulating particle flow" and "was unable to give any specific comparisons of the densities of bubbles as opposed to particles in the air."

ECF No. 739, Pl. Mem. at 8. Mr. Keen's lack of experience with "neutrally buoyant bubbles," however, does not preclude him from opining regarding the fact that bubbles are not the same as particles, and particles are not the same as bacteria. *See* ECF No. 740-1, Keen Rept. at 18-21. Mr. Keen reviewed several studies on this topic, including Plaintiffs' bubble studies and studies that measured "actual airborne bacterial contamination (as opposed to particles or helium bubbles)." *Id.* at 19; *see generally id.* at 13-21. Mr. Keen's research led him to conclude:

> The ability of a bubble to accurately represent a bacteria-laden particle in air is questionable. First of all, the size of the bubble is significantly larger, presenting a greater surface area to be impacted by airflow. Studies have also shown that bubbles are generally not reliable to accurately represent airflow.

Id. at 13. He further concludes that, based on his training, experience, and review of relevant literature, "the association between particles and organisms is far from being clearly established" and that, while the absence of an increase in particles can be a good indication of the absence of an increase in bacteria, the inverse "is not conclusive in determining the degree of microbial bioburden." *Id.* at 18-19.

Plaintiffs may not like Mr. Keen's opinions, but that does not mean he should not be permitted to offer them. "A litigant's mere disagreement with the expert's assumptions and methodology does not support exclusion of the expert's testimony." *Wood v. Robert Bosch Tool Corp.*, No. 4:13cv01888 TCM, 2015 WL 5638035, at *10 (E.D. Mo. Sept. 24, 2015), ("'Attacks on the foundation' of the expert's opinion and conclusions, and the completeness of the expert's methodology, go to the weight rather than the admissibility of the expert's testimony.") (internal citations omitted).

Plaintiffs similarly argue that Mr. Keen is not qualified to testify regarding the protective "thermal plume" generated by a patient that forms over the surgical site and helps to divert contaminated particles coming from operating room staff. *See* ECF No. 740-1, Keen Rept. at 16-17. Based on his experience and review of the relevant research, Mr. Keen opines that "a forced air warming device [like the Bair Hugger system] could have a similar protective effect" because it provides "an upward force bucking against the laminar flow field within a very short distance above the blanket." *Id.* at 17.

This is consistent with the purpose of the ASHRAE Standard 170 specifications for diffuser velocity (between 25 and 35 feet per minute), which is to provide enough of a downflow to blow contaminated particles to the side, without overcoming the patient's protective layer of heat – "the thermal plume" – and allowing contaminated particles to blow into the open wound. *See* DX3, ASHRAE Standard 170-2013 at 14, § 7.4.1; ECF No. 740-1, Keen Rept. at 4, 16-18. These specifications are based on the work performed by Dr. Farhad Memarzadeh's work on behalf of the National Institutes of Health (NIH). *See id.* Dr. Memarzadeh's work is also part of the underlying research studied and analyzed by Mr. Keen in forming his opinions. *See id.* at 16-17.

Indeed, Plaintiffs' own expert, Daniel Koenigshofer, acknowledged Dr. Memarzadeh's work in his deposition testimony:

> Q: [I]s there something about this particular velocity that's important, the 25 to 35 CFMs?
>
> A: Memarzadeh hypothesized about a wound plume.
>
> Q: Tell me about that. What does he mean by "wound plume?"

> A My understanding is that he felt like there's a small amount of heat coming off of an exposed part of the body, which would cause a convective updraft and that little thermal mushroom cloud would contain only the bugs from that patient. And, therefore, you do not want your velocity from your diffusers to be so great that it blows away that wound plume.

DX2, Deposition of Daniel Koenigshofer, P.E. ("Koenigshofer Dep.") at 133:18-134:12 (internal objections by counsel omitted). Although Koenigshofer claims he is "skeptical that the temperature of the wound would be sufficient to cause much of a mushroom cloud," he agrees that "a slight thermal updraft . . . would be protective for purposes of preventing surgical site infections." *Id.* at 135:3-10.

Plaintiffs argue that Mr. Keen should not be permitted to testify regarding the "thermal plume" or its benefits, claiming that he did not perform research or experimental work in the field prior to this litigation and "never calculated the buoyancy or the force of a thermal plume." ECF No. 739, Pl. Mem. at 7. According to Plaintiffs, Mr. Keen "merely regurgitates opinions offered by a single researcher [Dr. Farhad Memarzadeh] in a separate discipline," which Plaintiffs claim is prohibited by Fed. R. Evid. 703. *Id.* at 7-8 (citing *Dura Automotive Systems of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002)). Unlike in *Dura Automotive*, however, Mr. Keen is not simply parroting the opinions of another researcher or purporting to offer opinions outside his field of expertise. *See* 285 F.3d at 613. Indeed, Mr. Keen is expounding upon work with which he is quite familiar. Mr. Keen and Dr. Memarzadeh served together on the committee that developed ASHRAE Standard 170. *See* DX3, ASHRAE Standard 170-2013. The velocity specifications

incorporated in Standard 170 were informed by Dr. Memarzadeh's work on behalf of the NIH, which is also discussed in Mr. Keen's report and relied upon in forming his opinions. *See* ECF No. 740-1, Keen Rept. at 16-17; *see also* DX2, Koenigshofer Dep. at 136:3-137:11 (acknowledging that Dr. Memarzadeh's analysis was incorporated into ASHRAE Standard 170). Courts consistently recognize that such reliance is common, including the court in *Dura Automotive*. *See* 285 F.3d at 613 ("[I]t is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert."). It is thus entirely appropriate for Mr. Keen to rely upon the computational fluid dynamics research performed for the NIH by Dr. Memarzadeh, and such reliance does not render his opinion inadmissible. *See In re Mirena*, 169 F. Supp. 3d at 412. Plaintiffs' argument to the contrary is misguided.

Finally, Plaintiffs assert that Mr. Keen did not have an adequate foundation for his airflow opinions because (Plaintiffs assert) he relied "perhaps solely" on YouTube videos created by 3M to learn about how the Bair Hugger system works. *See* ECF No. 739, Pl. Mem. at 11-12. Plaintiffs are once again mischaracterizing Mr. Keen's deposition testimony. Mr. Keen testified that videos he viewed on YouTube simply provided further support for opinions he had already formed, based on his education, training, experience, and review of materials identified in his report:

> So, most of the … most of the videos that I looked at I am not relying upon for the basis of my opinions, but they were, again, as I tried to explain before the break, visualizations that were helpful to support what I was reading. So I didn't change…the videos didn't change my opinions but just helped as a visualization if that explains it better.

DX2, Keen Dep. at 253:2-10; *Wood v. Robert Bosch Tool Corp.*, 2015 WL 5638035, at *9 ("Importantly, demonstrated practical experience may qualify a person to be an expert witness."); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("Trained experts commonly extrapolate from existing data."); *See* Fed. R. Evid. 703 ("An expert may base an opinion on facts or data in the case *that the expert has been made aware of* or personally observed.") (emphasis added); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 (1993) ("Unlike an ordinary witness, an expert is permitted wide latitude to offer opinions, *including those that are not based on firsthand knowledge or observation*.") (emphasis added) (internal citations omitted).

IV. MR. KEEN'S OPINIONS AND TESTIMONY ARE GENERALLY ACCEPTED AND SATISFY THE REQUIREMENTS OF MINN. R. EVID. 702.

In addition to foundational reliability, Minnesota law further requires that an expert's opinions are generally accepted in the relevant scientific community. *See, e.g.*, *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). That standard is clearly satisfied here.

As set forth above, Mr. Keen's opinions and testimony are based on a comprehensive review of relevant scientific literature, as well as applicable ASHRAE standards. ASHRAE provides the benchmark for ventilation and filtration in United States hospitals and, clearly, is "generally accepted" in the scientific community. Mr. Keen's testimony is thus admissible under Minnesota law, as well as federal law.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion to exclude Mr. Keen's opinions and testimony should be denied. Mr. Keen is thoroughly qualified to give his opinions, and those opinions are relevant and reliable under Fed. R. Evid. 702 and Minn. R. Evid. 702. Mr. Keen's testimony will greatly aid the trier of fact by rebutting Plaintiffs' contentions concerning the filtration efficiency of the Bair Hugger system and its impact on operating room airflow.

Dated: October 3, 2017

Respectfully submitted,

s/Monica L. Davies

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